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EXAMINER	
DUFFY, BRADLEY	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,734	KUFER ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25 and 27-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment filed June 18, 2007, is acknowledged and has been entered. Claim 26 has been canceled. Claims 1, 3-23, 27 and 29-31 have been amended.

2. The amendment filed July 6, 2007, is acknowledged and has been entered.

3. Claims 1-31 are pending in the application and are currently subject to restriction.

Election/Restrictions

4. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-15, 23-25 and 31, insofar as the claims are drawn to bispecific binding molecules, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid

sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group II, claims 16-25 and 31, insofar as the claims are drawn to nucleic acid sequences encoding a bispecific binding molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group III, claims 27-30, insofar as the claims are drawn to a method for the

prevention, treatment or amelioration of a proliferative disease or a tumorous disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group IV, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of a proliferative disease or a tumorous disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid

sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group V, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of a proliferative disease or a tumorous disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in

the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group VI, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an inflammatory disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group VII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an inflammatory disease in a subject in the need thereof, said method comprising the step of administrating an

effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group VIII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an inflammatory disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence

encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group IX, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an immunological disorder in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group X, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an immunological disorder in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XI, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an immunological disorder in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at

least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an autoimmune disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a

result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XIII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an autoimmune disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XIV, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an autoimmune disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XV, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an infectious disease or viral disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of

SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XVI, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an infectious disease or viral disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino

acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XVII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an infectious disease or viral disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XVIII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an allergic reaction in a subject in the need thereof, said method comprising the step of administrating an

effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XIX, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an allergic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid

sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XX, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of an allergic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one

further antigen-interaction-site and/or at least one further effector domain.

Group XXI, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of a parasitic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of a parasitic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex,

wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXIII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of a parasitic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide

sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXIV, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of graft-versus-host disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXV, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of graft-versus-host disease in a

subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXVI, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of graft-versus-host disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded

by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXVII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of host-versus-graft disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the

Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XVIII, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of host-versus-graft disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Group XXIX, claims 27-30, insofar as the claims are drawn to a method for the prevention, treatment or amelioration of host-versus-graft disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector

comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

5. The inventions listed as Groups I-XXIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. The technical feature recited in claim 1 is bispecific binding molecules, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with

the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

This claim lacks an inventive step over WO 96/26964 A1 (Weiner et al, 1996. IDS filed 8/8/06)). Weiner et al discloses bispecific anti-CD3 and anti-ID 10 antibodies, wherein humanized anti-CD3 antibody M291 light chain variable region is 91 % identical to SEQ ID NO:2. Accordingly, since such a nucleotide encoding said region would bind to a nucleic acid encoding amino acid sequence of SEQ ID NO: 2 under stringent conditions, Weiner et al teach the technical feature recited in claim 1, and it is not a special technical feature and the groups do not relate to a single general inventive concept as required under PCT Rule 13.1.

For these reasons, the special technical feature of the invention of Group I is making Group I is making a bispecific binding molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the

proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group II is making a nucleic acid sequences encoding a bispecific binding molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group III is preventing, treating or ameliorating a proliferative disease or a tumorous disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence

is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group IV is preventing, treating or ameliorating a proliferative disease or a tumorous disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector

domain.

The special technical feature of the invention of Group V is preventing, treating or ameliorating a proliferative disease or a tumorous disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group VI is preventing, treating or ameliorating an inflammatory disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a

nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group VII is preventing, treating or ameliorating an inflammatory disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group VIII is preventing, treating or ameliorating an inflammatory disease in a subject in the need thereof,

said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group IX is preventing, treating or ameliorating an immunological disorder in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of

the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group X is preventing, treating or ameliorating an immunological disorder in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XI is preventing, treating or ameliorating an immunological disorder in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a)

wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XII is preventing, treating or ameliorating an autoimmune disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96

according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XIII is preventing, treating or ameliorating an autoimmune disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XIV is preventing, treating or ameliorating an autoimmune disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino

acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XV is preventing, treating or ameliorating an infectious disease or viral disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XVI is preventing, treating or ameliorating an infectious disease or viral disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XVII is preventing, treating or ameliorating an infectious disease or viral disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with

the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XVIII is preventing, treating or ameliorating an allergic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XIX is preventing, treating or ameliorating an allergic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic

acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XX is preventing, treating or ameliorating an allergic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one

of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXI is preventing, treating or ameliorating a parasitic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXII is preventing, treating or ameliorating a parasitic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with

the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXIII is preventing, treating or ameliorating a parasitic reaction in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a

second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXIV is preventing, treating or ameliorating graft-versus-host disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXV is preventing, treating or ameliorating graft-versus-host disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid

sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXVI is preventing, treating or ameliorating graft-versus-host disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXVII is

preventing, treating or ameliorating host-versus-graft disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XVIII is preventing, treating or ameliorating host-versus-graft disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a nucleic acid molecule encoding a bispecific binding molecule or a vector comprising said nucleic acid molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under

stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

The special technical feature of the invention of Group XXIX is preventing, treating or ameliorating host-versus-graft disease in a subject in the need thereof, said method comprising the step of administrating an effective amount of a host cell comprising a vector comprising a nucleic acid molecule encoding a bispecific molecule, whereby said molecule comprises at least two domains, (a) wherein one of said at least two domains specifically binds to/interacts with the human CD3 complex, wherein said domain comprises an amino acid sequence of an antibody derived light chain, wherein said amino acid sequence is (i) an amino acid sequence of SEQ ID NO: 2; (ii) an amino acid sequence encoded by a nucleic acid sequence corresponding to SEQ ID NO: 1; (iii) an amino acid sequence encoded by a nucleotide sequence hybridizing with the complementary strand of a nucleic acid sequence as defined in (ii) under stringent conditions; and (iv) an amino acid sequence encoded by a nucleic acid sequence which is degenerate as a result of the genetic code to a nucleotide sequence of any one of (ii) and (iii) with the proviso that amino acid sequences according to (i) to (iv) comprise amino acid substitutions in the CDR regions of the light chain in positions L24, L54 and L96 according to the Kabat system; and (b) wherein a second domain is or contains at least one further antigen-interaction-site and/or at least one further effector domain.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

6. This application contains claims directed to more than one species of the generic invention of Group I, wherein the bispecifc molecule comprises a domain comprising the amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, NO:34, SEQ ID NO:36, the amino acid sequence encoded by SEQ ID NO:1, the amino acid sequence encoded by SEQ ID NO:3, the amino acid sequence encoded by SEQ ID NO:5, the amino acid sequence encoded by SEQ ID NO:7, the amino acid sequence encoded by SEQ ID NO:9, the amino acid sequence encoded by SEQ ID NO:13, the amino acid sequence encoded by SEQ ID NO:15, the amino acid sequence encoded by SEQ ID NO:17, the amino acid sequence encoded by SEQ ID NO:21, the amino acid sequence encoded by SEQ ID NO:23, the amino acid sequence encoded by SEQ ID NO:25, the amino acid sequence encoded by SEQ ID NO:27, the amino acid sequence encoded by SEQ ID NO:29, the amino acid sequence encoded by SEQ ID NO:31, the amino acid sequence encoded by SEQ ID NO:33 and the amino acid sequence encoded by NO:35,

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

7. Accordingly, if Group I is elected Applicant is required, in reply to this action, to elect a single species of domain that specifically binds to/interacts with the human CD3 complex to which the claims shall be restricted if no generic claim is finally held to be allowable. Notably, if the elected sequence is encoded by a claimed nucleic acid sequence SEQ ID NO, or vice versa, Applicant is request identify both sequences. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional

species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

In this case, the prior art of Weiner et al (see above) teach a bispecifc molecule structurally and materially indistinguishable from the claimed bispecifc molecule. Accordingly, each bispecifc molecule comprising a different amino acid sequence is structurally distinct and has a different special technical feature because the different species are not linked to form a single general inventive concept under PCT Rule 13.1 by the clamed bispecifc molecule.

Therefore, the different species do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

9. This application contains claims directed to more than one species of the generic invention of Group I, wherein the second domain specifically binds to/interacts with an antigen selected from the group consisting of EpCAM, CCR5, CD19, HER-2, HER-3, HER-4, EGFR, PSMA, CEA, MUC-1 (mucin), MUC2, MUC3, MUC4, MUC5AC, MUC5B, MUC7, bhCG, Lewis-Y, CD20, CD33, CD30, ganglioside GD3, 9-0- Acetyl-GD3, GM2, Globo H, fucosyl GM1, Poly SA, GD2, Carboanhydrase IX (MN/CA IX), CD44v6, Sonic Hedgehog (Shh), Wue-1, Plasma Cell Antigen, (membrane-bound) IgE, Melanoma Chondroitin Sulfate Proteoglycan (MCSP), CCR8, TNF-alpha precursor, STEAP, mesothelin, A33 Antigen, Prostate Stem Cell Antigen (PSCA), Ly-6 desmoglein 4, E- cadherin neoepitope, Fetal Acetylcholine Receptor, CD25, CA 19-9 marker, CA- 125 marker and Muellerian Inhibitory Substance (MIS) Receptor type II, sTn (sialylated Tn antigen; TAG-72), FAP (fibroblast activation antigen), endosialin,

EGFRvIII, L6, SAS, CD63, TF- antigen, Cora antigen, CD7, CD22, Iga, Ig13, gp100, MT-MMPs, F 19-antigen and CO-29.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

10. Accordingly, if Group I is elected Applicant is required, in reply to this action, to elect a single species of second as set forth above to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Notably, PCT Rule 13.2 sets forth that claimed alternatives are linked by a special technical feature when the alternatives are of a similar nature. PCT Rule 13.2 further sets forth that alternatives are of a similar nature when:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In this case, while each species binds to a different antigen, so each alternative does not have a common property or activity.

For these reasons, each species of agent set forth above is not deemed to share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

12. This application contains claims directed to more than one species of the generic invention of Group II, wherein the nucleic acid comprises a nucleotide sequence encoding the mature form of a protein comprising the amino acid sequence of SEQ ID NO: 20, a nucleotide sequence encoding the mature form of a protein comprising the amino acid sequence SEQ ID NO: 34, a nucleotide sequence encoding the mature form of a protein comprising the amino acid sequence SEQ ID NO: 36, a nucleotide sequence comprising or consisting of a DNA sequence of SEQ ID NO: 19, a nucleotide sequence comprising or consisting of a DNA sequence of SEQ ID NO: 33 or a nucleotide sequence comprising or consisting of a DNA sequence of SEQ ID NO: 35.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

13. Accordingly, if Group II is elected Applicant is required, in reply to this action, to elect a single species of second as set forth above to which the claims shall be restricted if no generic claim is finally held to be allowable. Notably, if the elected sequence is encodes a recited amino acid sequence SEQ ID NO, or vice versa, Applicant is request identify both sequences. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Notably, PCT Rule 13.2 sets forth that claimed alternatives are linked by a special technical feature when the alternatives are of a similar nature. PCT Rule 13.2 further sets forth that alternatives are of a similar nature when:

(A) All alternatives have a common property or activity; and

(B)(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In this case, while each species is structurally and functionally distinct, so each alternative does not have a common property or activity.

For these reasons, each species of agent set forth above is not deemed to share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

15. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a single invention to be examined and an election of the species of invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention and the elected species of invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply

does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112.

Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Misook Yu, can be reached at (571) 272-0839. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
September 7, 2010